

SWITCHING TO THE 2-DRUG REGIMEN OF DOLUTEGRAVIR/LAMIVUDINE (DTG/3TC) FIXED-DOSE COMBINATION (FDC) IS NON-INFERIOR TO CONTINUING A 3-DRUG REGIMEN THROUGH 24 WEEKS IN A RANDOMIZED CLINICAL TRIAL (SALSA)

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Background:

Long-term non-inferior efficacy of the 2-drug regimen (2DR) dolutegravir/lamivudine (DTG/3TC) compared with 3/4-drug regimens (3/4DRs) has been demonstrated in treatment-naïve (DTG + tenofovir disoproxil fumarate/emtricitabine through 144 weeks) and treatment-experienced individuals with HIV-1 (tenofovir alafenamide-based regimens through 96 weeks), with a good safety profile and high barrier to resistance.

Methods:

SALSA is an open-label study of participants with HIV-1 RNA <50 copies/mL for >6 months on a 3/4DR without prior virologic failure or nucleoside reverse transcriptase inhibitor or DTG resistance-associated mutations, randomized 1:1 (stratified by baseline third agent class) to switch to DTG/3TC or continue their current antiretroviral regimen (CAR) for 52 weeks. Primary endpoint was proportion of participants with plasma HIV-1 RNA ≥50 copies/mL at Week 48 (Snapshot algorithm). Planned Week 24 interim analysis assessed non-inferiority (5% margin). Estimates and confidence intervals (CIs) were based on a stratified analysis using Cochran-Mantel-Haenszel weights adjusting for baseline third agent class.

Results:

493 participants were randomized (59% white; 39% women; 39% aged >50 years). DTG/3TC was non-inferior to continuing CAR at Week 24 using Snapshot virologic failure (DTG/3TC, 0% [0/246]; CAR, <1% [1/247]; adjusted treatment difference [95% CI], -0.4% [-1.2%, 0.4%]); results were consistent using Snapshot virologic success (DTG/3TC, 95% [234/246]; CAR, 96% [237/247]; adjusted treatment difference [95%

CI], -0.8% [-4.5%, 2.8%]). No participants met confirmed virologic withdrawal criteria; therefore, no resistance testing was done. Overall safety outcomes were comparable between DTG/3TC and CAR groups for frequency of adverse events (AEs; 60% vs 60%), AEs leading to withdrawal (2% vs <1%), and serious AEs (1% vs 6%), respectively.

Conclusion:

Switching to DTG/3TC was non-inferior to continuing CAR in maintaining virologic suppression at Week 24, with a safety profile consistent with the DTG and 3TC labels. The study is ongoing; the conference presentation will include lipid data and Week 48 results.

Disclosure of Interest Statement:

JM Llibre has received personal fees for advisory board participation from ViiV Healthcare, Gilead Sciences, and Janssen Pharmaceutica. C Alves has served as a speaker and advisory board member for GSK, Gilead, Janssen, and Merck. L Hocqueloux has received personal fees and non-financial support from Gilead, Janssen, Merck Sharp & Dohme, and ViiV Healthcare, outside the submitted work. F Maggiolo has received research funding from ViiV Healthcare, Gilead Sciences, Merck, Janssen, and AbbVie and has received personal fees for participation in advisory boards from ViiV Healthcare, Gilead Sciences, and Merck. O Degen, C-Y Cheng, O Osiyemi, and C Galera have nothing to disclose. L Blair, B Wynne, M Underwood, G Bontempo, J van Wyk and A Maccarrone are employees of ViiV Healthcare and may own stock in GlaxoSmithKline. J Oyee and L Curtis are employees of and may own stock in GlaxoSmithKline. This study was funded by ViiV Healthcare.